

Recommendation of Division Directors Negotiated Due Dates					
Decision #: 493777		Registration #: 62719-649		Petition #: 4F8303	
<input type="checkbox"/> See page 2 for additional registration entries					
Chemical Name: 2,4-D and Glyphosate					
Fee Category: R170				PRIA Decision Time Frame: 15 months	
Submitted by: Emily		A Schmid		Branch: OCSPP/OPP/RD	Date: 10/22/2015
Company: Dow Agrosiences LLC					
Original PRIA Due Date: 11/20/2015			Proposed New PRIA Due Date: 05/20/2016		
Previous Negotiated Due Dates:					
Is the "Fix" in-house?		<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> n/a		If not, date "Fix" expected: 11/01/2015	
Negotiated Due Date Reason:					
Additional Data Required	<input type="checkbox"/> Product Chemistry	<input type="checkbox"/> Toxicology	<input type="checkbox"/> Acute Tox	<input type="checkbox"/> Environmental	
	<input type="checkbox"/> Efficacy	<input type="checkbox"/> Ecological	<input type="checkbox"/> Residue	<input checked="" type="checkbox"/> Other	
Data Deficiencies	<input type="checkbox"/> Product Chemistry	<input type="checkbox"/> Acute Tox	<input type="checkbox"/> Efficacy	<input type="checkbox"/> Residue	<input type="checkbox"/> Toxicology
	<input type="checkbox"/> Environmental	<input type="checkbox"/> Ecological	<input type="checkbox"/> Labeling	<input type="checkbox"/> Other	<input type="checkbox"/> Not Submitted
Late Risk Assessment	<input type="checkbox"/> Human Health	<input type="checkbox"/> Ecological			
Interim Consideration	<input type="checkbox"/> Agency Initiated		<input type="checkbox"/> Registrant Initiated		
<input type="checkbox"/> CSF	<input type="checkbox"/> Public Process	<input type="checkbox"/> Risk Issues Environmental	<input type="checkbox"/> Risk Issues Human Health		
<input type="checkbox"/> Impurities Review	<input type="checkbox"/> Label	<input type="checkbox"/> Administrative-FR Notice	<input type="checkbox"/> Other – Comment Field		
Summary of Deficiency Type(s): <input type="checkbox"/> Not Submitted (N) <input type="checkbox"/> Deficiencies (D)					
Product Chemistry: <input type="checkbox"/> Acute Tox: <input type="checkbox"/> Efficacy: <input type="checkbox"/> Labeling: <input type="checkbox"/> Ecological Data: <input type="checkbox"/> Other (describe): <input checked="" type="checkbox"/>					
Synergy data requested via 6(a)(2) letter to registrant.					
Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):					
On 10/13/2015, a 6(a)(2) letter was emailed to DAS advising them that the Agency needs data regarding the claims of synergism made in their patent application filed on 12/11/2014. A follow up meeting with DAS took place on 10/20/2015 to clarify what data needs to be submitted to the Agency.					
"75 Day" Letter sent? <input type="checkbox"/> Yes, Date sent <input checked="" type="checkbox"/> No and reason for none? <i>Add comments on page 2</i>					
Rationale for Proposed Due Date: Allows time for DAS to submit data and EFED to review.					
Registrant notified that this is the last negotiation? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> Not Applicable					
Approve: <input checked="" type="checkbox"/>			Disapprove: <input type="checkbox"/>		
If disapproved, action to be taken:					
OD or DOD Signature: CN=Marty Monell/OU=DC/O=USEPA/C=US				Date: 10/22/2015	

⑥
3 pages

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Issue(s) (describe in detail):

On 12/11/2014, DAS filed a patent application claiming synergistic herbicidal weed control when using a mixture of 2,4-D choline salt and glyphosate. This claim raised concerns of a potential impact on the assessment of drift reduction measures that were used to set a spray drift buffer of 30 feet to avoid non-target organisms. A 6(a)(2) letter was emailed to DAS on 10/13/2015 requesting related data be submitted to the Agency in order for us to further review this claim and ensure the 30 foot buffer is adequate. A 6 month extension to the PRIA date is requested in order for EFED to receive and review the data and allow time for RD to proceed with the public process if found acceptable.

Comment(s):

Audit Trail for

Recommendation of Division Directors Negotiated Due Dates

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